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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,570	11/01/2001	Martyn Frank Burslem	PCS10895ANIS	2725

7590 10/29/2002

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EXAMINER
BERTOGLIO, VALERIE E

ART UNIT	PAPER NUMBER
1632	8

DATE MAILED: 10/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/040,570	Applicant(s) BURSLEM ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *30days* ~~MONTH~~(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Election/Restriction* .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, drawn to genetically-modified, non-human mammal with a disruption in the PDE11A gene, classified in class 800, subclass 14.

II. Claims 4-7, drawn to a cell with a disruption in the PDE11A gene, classified in class 435, subclass 324.

III. Claims 8 and 9, drawn to an in vitro method of identifying an agent using PED11A polypeptide, classified in class 530, subclass 350.

IV. Claim 10, drawn to an in vitro method of identifying an agent that modulates spermatogenesis using cells expressing PDE11A, classified in class 435, subclass 325.

V. Claims 11-17, drawn to a method of modulating spermatogenesis using an agent that modulates PDE11A activity using UK-336,017 (IC-351), UK-227,786 (E4021), or UK-235,187, unclassifiable.

VI. Claims 18-20, drawn to a method of detecting the modulation of spermatogenesis, classified in various classes and subclass.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because, the transgenics can be used as an in vivo animal model for disease while the cells can be used in vitro to study the effects of PDE11A disruption on gene expression. The protocols and reagents required for the transgenic and the

cells are materially distinct and separate. The transgenic does not require the cells and the cells do not require the transgenic.

Inventions I and III or IV are patentably distinct because, the transgenics can be used as an in vivo animal model for disease while the methods can be used in vitro to identify agents that modulate PDE11A activity. The protocols and reagents required for the transgenic and the methods are materially distinct and separate. The transgenic does not require the methods and the methods do not require the transgenic.

Inventions I and V are patentably distinct because, the transgenics can be used as an in vivo animal model for disease while the methods can be used to modulate spermatogenesis. The protocols and reagents required for the transgenic and the methods are materially distinct and separate. The transgenic does not require the methods and the methods do not require the transgenic.

Invention I and VI are patentably distinct because, the transgenics can be used as an in vivo animal model for disease while the methods can be used to detect the modulation of spermatogenesis. The protocols and reagents required for the transgenic and the methods are materially distinct and separate. The transgenic does not require the methods and the methods do not require the transgenic.

Inventions II and III or IV are patentably distinct because the PDE deficient cells can be used to determine the effect is PDE11A disruption on gene expression while the methods can be used identify modulators of PDE11A activity. The protocols and reagents required for the cells and the methods are materially distinct and separate. The cells do not require the methods and the methods do not require the cells.

Inventions II and V are patentably distinct because the PDE deficient cells can be used to determine the effect of a PED11A disruption on gene expression while the methods can be used modulate spermatogenesis. The protocols and reagents required for the cells and the methods are materially distinct and separate. The cells do not require the methods and the methods do not require the cells.

Invention II and VI are patentably distinct because the PDE deficient cells can be used to determine the effect of a PED11A disruption on gene expression while the methods can be used detect modulation of spermatogenesis. The protocols and reagents required for the cells and the methods are materially distinct and separate. The cells do not require the methods and the methods do not require the cells.

The methods of each of inventions III-VI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Invention III uses a PDE11A polypeptide to identify an agent, Invention IV uses a PDE11A expressing cell to identify an agent, Invention V uses an agent to modulate spermatogenesis, and Invention VI is a method of detecting modulation of spermatogenesis. The burden required to search inventions III-VI together would be undue.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Group VI contains claims directed to the following patentably distinct species of the claimed invention:

a) measuring the expression of the biomarker Corticosteroid binding globulin (claims 18-20);

b) measuring the expression of the biomarker Centrin 3 (claims 18-20);

c) measuring the expression of the biomarker XRCC1 (claims 18-20);

d) measuring the expression of the biomarker Chromobox M33 (claims 18-20);

e) measuring the expression of the biomarker GABA-A (gamma 3 sub-unit) (claims 18-20);

f) measuring the expression of the biomarker Prohormone convertase 5 (claims 18-20);

g) measuring the expression of the biomarker Leydig Insulin-like peptide (claims 18-20);

h) measuring the expression of the biomarker Calpain 3 (claims 18-20);

i) measuring the expression of the biomarker Y-Box 3 (claims 18-20);

j) measuring the expression of the biomarker Chromogranin B (claims 18-20);

k) measuring the expression of the biomarker Cryptdin I (claims 18-20);

l) measuring the expression of the biomarker PP2B (claims 18-20);

m) measuring the expression of the biomarker Glutamate cysteine ligase (claims 18-20);

n) measuring the expression of the biomarker Nidogen (claims 18-20);

o) measuring the expression of the biomarker HR6A (claims 18-20);

p) measuring the expression of the biomarker Protamine 1 (claims 18-20);

q) measuring the expression of the biomarker sp32 (claims 18-20);

r) measuring the expression of the biomarker mCDC46 (claims 18-20);

s) measuring the expression of the biomarker adenylate kinase 2 (claims 18-20);

t) measuring the expression of the biomarker AKAP121 (claims 18-20);

u) measuring the expression of the biomarker Krox-24 binding protein (claims 18-20).

If applicants elect Group VI, applicants are required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner

MICHAEL C. WILSON
PATENT EXAMINER